

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/007998

International filing date (day/month/year)
09.07.2004

Priority date (day/month/year)
11.07.2003

International Patent Classification (IPC) or both national classification and IPC
A61J7/04, A61J7/02

Applicant
GLAXO GROUP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Form PCT/ISA/237 (Cover Sheet) (January 2004)

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**WRITTEN OPINION OF THE
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed; unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 32,33

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 32,33
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

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Box No. V Reasoned statement under Rule 43b/s.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	23-28
	No: Claims	1-22,29-31
Inventive step (IS)	Yes: Claims	24-28
	No: Claims	1-23,29-31
Industrial applicability (IA)	Yes: Claims	1-31
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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Re Item III**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

- 1 Claims 32 and 33 rely on references to the drawings. According to Rule 6.2 (a) PCT these claims are not allowable.

Re Item V**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 2 The following documents are referred to in this communication:

D1 : GB 2 233 317 A (GAD JONATHAN NOAH) 9 January 1991 (1991-01-09)
D2 : US 5 805 051 A (WANG SUNWAY R ET AL) 8 September 1998 (1998-09-08)
D3 : EP-A-0 629 563 (LILLY INDUSTRIES LTD) 21 December 1994 (1994-12-21)

- 3 The present application does not meet the criteria of Article 33(1) PCT.

- 3.1 The document D1 discloses (page 1, last paragraph, page 2 - page 3, figures 2, 5) (the references in parentheses applying to this document):

A hand-held dispenser suitable for dispensing a multiplicity of unit products having a storage area (10) for storing the unit products, an outlet opening (7) through which the unit products are dispensable from the dispenser, a dispensing mechanism actuatable to dispense the unit products through the outlet opening (7), and a timing mechanism adapted in use to time the period since last dispensing of a unit product.

Document D3 also discloses a hand-held dispenser with all the technical features of claim 1.

Therefore, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

- 3.2 Dependent claims 1 to 23 and 29, 30 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

Novelty

D1, page 1, last paragraph, page 2 - page 3, figures 2, 5; for claims 2 - 6, 15 - 22, 29, 30

D2, column 3, line 52 - column 5, line 22; figures 1 - 7; for claims 7 -14

Inventive step

D3, page 4, line 40 - page 5, line 8, figures 15 - 20, for claim 23. A releasable attachment of the two dispenser parts is commonplace in the present technical field.

3.3 The subject matter of independent claim 31 is also disclosed in D1. Since claim 31 only claims a part of the subject matter of claim 22, the same reasoning as the one given in conjunction with claim 22 applies to the subject-matter of claim 31, which therefore is also considered not new.

3.4 The combination of the features of dependent claim 24 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

The subject-matter of claim 24 differs from this known D1 in that the dispenser has a closure which is selectively connectable with the first and second dispenser parts.

The problem to be solved by the present invention may be regarded as to allow the second part to be use with standard pill bottles (page 7, line 26 - page 8, line 2)

The solution to this problem proposed in claim 24 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The closure on a pill bottle (first part) can be replaced by the attachable dispenser module (second part) and the closure can be used to close the dispenser including the two parts.

Claims 25 -28 are dependent on claim 24 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

4 Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT,

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which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

- 5 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
- 6 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).